REMARKS

Applicants have carefully considered the Examiner's comments in the Office Action dated March 19, 2003, and respond as follows.

Applicants note that the Examiner has stated, on page 3, first full paragraph, that "the invention is drawn to compositions that have RAR antagonist [activity] having specific RAR modulating activity and a method of using such compositions." This is incorrect. Applicants have stated in the previous two pieces of correspondence, and again state here, that the pending claims are solely drawn to methods using an RARβ antagonist having specific RAR modulating activity. There are no composition claims currently pending.

Rejections Pursuant to 35 USC §112(1)

The Examiner has rejected claims 13-28 as allegedly failing to comply with the written description requirement. Applicants traverse this rejection.

The Examiner allege as this is so because the "scope of the claims is unknown due to the structural limitations not being specifically disclosed." Page 2 of the September 15, 2003 Office Action. However, clarity is not the job of the description requirement, whose purpose is to "put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use or is already known. . . ." *Vas Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). The present method claims currently accomplish this by clearly setting forth a method for the treatment or prevention of lung diseases using a selective RARβ antagonist.

The *PTO Final Examiner Guidelines on Written Description Requirement*, 66 Fed. Reg. 1099 (BNA Patent, Trademark and Copyright J., January 12, 2001) (hereinafter the "Guidelines") indicate that there is not just a presumption, but a strong presumption, that an adequate written description of the claimed invention is present when the application is filed, and that "an originally filed claim is its own written description". Guidelines, comment 3. Under the Guidelines, the "burden is on the Examiner to establish that description as filed is not adequate and . . . to introduce sufficient evidence or technical reasoning to shift the burden" to the Applicant. *Id.*

Present independent claim 13 has been amended in two ways. First, to reintroduce the limitation, present in originally filed claim 13 and inadvertently omitted through a typographical error, that said RAR antagonist is an RAR antagonist. Thus, this amendment merely makes the claim consistent with its original language. The second way in which claim 13 was amended was in the addition of the limitation herein "such antagonist is not specific to at least

one other RAR receptor subtype". However, this limitation is inherently present in the aggregate in originally filed claims 14, 15 and 16, and thus does not constitute new matter.

Furthermore, claim 21 has never been amended, and is thus an originally filed claim in the entirety.

Applicants respectfully submit that the Examiner has not overcome the strong presumption that these claims are adequately supported by a written description. As has been described in prior communications by Applicants, the specification describes (including in the US patents incorporated by reference) numerous compounds which can be used in the claimed methods. The Examiner has already conceded that these patented RAR antagonists are enabled. October 31, 2002 Office Action at page 2. Such compounds constitute many thousands of structurally diverse compounds, including: aryl-and heteroarylcyclohexenyl substituted alkenes, benzo 1,2-chrom-3-ene and benzo1,2-thiochrom-3-ene compounds, N-aryl substituted tetrahydroquinolines, and aryl-substituted and aryl and (3-oxo-1-propenyl)-substituted benzopyran, benzothiopyran, 1,2-dihydroquinoline, and 5,6-dihydronaphthalene derivatives.

Clearly, these compounds cannot be enabled without being adequately described. Applicants submit that these numerous patent compounds disclosed herein comprise an adequate description of a representative number of embodiments of the present claimed methods, certainly sufficient to inform the person of skill in the art that Applicants were in possession of the invention. The Guidelines remind us that "patents and printed publications in the art should be relied on to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies where . . . the level of knowledge and skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. " Guidelines at 1106. For these reasons Applicants respectfully request reconsideration of this rejection.

Enablement

The Examiner has rejected claims 13-28, alleging that the pending method claims are not enabled by the specification such that a person of ordinary skill in the art could make or use them.

In support of her position, the Examiner has cited factors cited in *In re Wands,* 8 USPQ2d 1400 (Fed. Cir. 1988) in an attempt to establish that compounds that are RAR specific and have RARβ antagonist activity (i.e., those used in the claimed methods) can only be found through undue experimentation.

Applicants firstly note that these factors are not "the" test for enablement. The Court of Appeals for the

Federal Circuit have made clear that "the *Wands* factors are illustrative, not mandatory. What is relevant depends on the facts". *Enzo Biochem Inc. v. Calgene, Inc.,* 52 USPQ2d 1129 (Fed. Cir. 1999). The test for enablement thus remains whether the specification teaches person of skill in the art would know how o make and use the invention, as claimed, without undue experimentation.

As mention in the Reply filed January 31, 2003, the Examiner concedes that the RAR antagonists disclosed in the patents incorporated by reference within this application are enabled. October 31, 2002 Office Action at page 2. The January Reply is hereby incorporated by reference.

The Examiner continues to state that "the only compounds that are enabled by the instant specification have already been patented". To the extent this is true, it is completely irrelevant to the currently pending method claims. Indeed, this argument only strengthens Applicants' assertion that these method claims are indeed enabled.

Because the prior art (including that expressly incorporated by reference herein) discloses a vast variety of β RAR antagonists, because methods of finding additional RAR β antagonists are routine in the art and because suitable methods of administration are both well known and described in the specification, the person of ordinary skill in the art would clearly be able to make and use the present invention without undue experimentation.

Rejection Pursuant to 35 USC 102(b)

The Examiner has again rejected claims 13-28 as anticipated by each of Ghaffari, Cong, Xu, Wu, Co, Song, and Yu with little or no explanation. The Examiner argues that all these references "disclose RAR modulation and lung tissues". Applicants traverse these rejections.

Applicants do not claim RAR modulation and lung tissues. Each of the pending method claims contains specific limitations. The Examiner has not met her burden of showing Applicants how each cited reference contains, either literally or implicitly, each and every limitation of the claim at issue. See e.g., *In re Paulson*, 31 USPQ2d 1671 (Fed. Cir. 1994).

In particular, the Examiner has not shown that any of the references disclose a method for the treatment or prevention of alveolar destruction by using an RAR-specific RAR β antagonist. The Applicant last asked that if the Examiner has found an anticipatory disclosure of each and every limitation of any of the present claims in one or more of these references, the Examiner expressly point to such disclosure. The Examiner has not done so to date; instead, the Examiner has merely stated "the prior art teaches a method for treating the same conditions as is instantly claimed." September 15, 2003 Office Action at 7. Applicants, following a detailed review of each

reference, do not see that this is true anywhere in any of the cited references, and do not believe the present claims are anticipated.

With respect, Applicants submit that the Examiner's reply thus does not meet the requirements of 37 CFR 1.104(b)(2), which states "in rejecting claims for want of novelty . . . the particular part [of a complex reference] replied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified." Applicants therefore kindly request the Examiner to reconsider and either withdrawn the rejections, or clearly point out the allegedly novelty-destroying passages in each reference.

CONCLUSION

For these reasons, Applicants respectfully submit that the claims are in condition for allowance, and respectfully request that the Examiner issue a Notice to that effect. Should any fees (such as an extension of the time to reply) be due in with this Reply, please use our Deposit Account No. 01-0885.

Respectfully submitted,

Dated: 12/12/03

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